UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Wave 9** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ***Cases Listed in Plaintiffs' Exhibit A***	

DEFENDANTS' OPPOSITION TO AND MOTION TO STRIKE PLAINTIFFS' UNTIMELY *DAUBERT* MOTION

Defendants Ethicon, Inc., and Johnson & Johnson submit this opposition to Plaintiffs' motion to exclude the expert testimony of Peter Jeppson, M.D. Docs. 8324 & 8325. As to the two Wave 10 Plaintiffs listed on Plaintiffs' Exhibit A, the motion is untimely and should be stricken and/or denied as moot. The motion also fails on the merits and should be denied, as explained more fully below.

Background

Plaintiffs Karen Johnson, Jeanette Poff, and Barbara Paris submitted their motion to exclude the expert testimony of Peter Jeppson, M.D., on June 3, 2019. Docs. 8324 & 8325.

Pursuant to Pretrial Order No. 320 ("PTO 320"), the deadline for filing *Daubert* motions in Wave 10 cases was May 13, 2019. Doc. 7173 at 3. Plaintiffs Jeannette Poff (Case No. 2:14-cv-28294) and Barbara Paris (Case No. 2:15-cv-12479) are part of Wave 10. *See id.* at Ex. A.

Pursuant to Pretrial Order No. 315 ("PTO 315"), the deadline for filing *Daubert* motions in Wave 9 cases was June 3, 2019. Doc. 6591 at 3. Plaintiff Karen Johnson (Case No. 2:15-cv-12633) is part of Wave 9. *See id.* at Ex. A.

Argument

I. The *Daubert* motion is untimely for the Wave 10 Plaintiffs and should be stricken and/or denied as moot.

In PTO 320, this Court set the deadline for filing *Daubert* motions for Wave 10 plaintiffs, such as Jeannette Poff and Barbara Paris, as May 13, 2019. Doc. 7173 at 3. "[A] scheduling order under Rule 16(b) is not a frivolous piece of paper, idly entered, which can be cavalierly disregarded by counsel without peril. . . . Indeed, a scheduling order is the critical path chosen by the trial judge and the parties to fulfill the mandate of Rule 1 in 'securing the just, speedy, and inexpensive determination of every action.'" *Price v. Marsh*, No. 2:12-cv-05442, 2013 WL 5409811 at *2 (S.D.W. Va. Sept. 25, 2013) (Goodwin, J.) (internal citation omitted) (quoting *Marcum v. Zimmer*, 163 F.R.D. 250, 253 (S.D. W. Va. 1995)). "Pretrial orders—and the parties' compliance with those orders and the deadlines set forth therein—are the engine that drives disposition on the merits. And a willingness to resort to sanctions in the event of noncompliance can ensure that the engine remains in tune, resulting in better administration of the vehicle of multidistrict litigation." *Drake v. Ethicon, Inc.*, No. 2:12-cv-00747, 2016 WL 1621954, at *2 (S.D.W. Va. Apr. 21, 2016) (internal quotation marks and citations removed).

Plaintiffs Poff and Paris filed their *Daubert* motion on June 3, 2019, well after the expiration of their May 13 deadline. *See* Doc. 8324. Plaintiffs did not seek an extension of the deadline or demonstrate good cause and excusable neglect for failing to comply with the Court's schedule. *See* Fed. R. Civ. P. 6(b); *In re Am. Nurses Ass'n*, No. 15-1481, 2016 WL 1381352, at *1 (4th Cir. Apr. 7, 2016). Thus, their motion should be stricken and/or denied as moot, because it was not timely filed. *Fed. Trade Comm'n v. Ramey Motors, Inc.*, No. 1:14-cv-29603, 2015 WL 13414426, at *1 (S.D.W. Va. Apr. 17, 2015) (denying as moot a motion to dismiss filed outside the Court's scheduled deadlines).

II. Plaintiffs' motion should be denied on the merits.

Plaintiff Karen Johnson, whose case is part of Wave 9, did timely file her *Daubert* motion pursuant to PTO 315. Her motion should be denied on the merits, because Dr. Jeppson is qualified to offer expert testimony. Defendants also argue in the alternative that the Wave 10 Plaintiffs' motion should be denied on the merits, if not dismissed as untimely.

A. Dr. Jeppson is qualified to opine as to the risks known to pelvic surgeons.

Plaintiffs argue that Dr. Jeppson is not qualified to offer opinions regarding the adequacy of risk information given in the product label and instructions for use ("IFU"). Doc. 8325 at 4-8. Dr. Jeppson is a urogynecologist at the University of New Mexico, where he is an Assistant Professor and Director of the Division of Urygynecology. General Report of Peter Jeppson, M.D., attached as Exhibit B to Plaintiffs' Motion, Doc. 8324-2 ("Report"), at 2. He is board-certified in obstetrics and gynecology as well as the specialty of Female Pelvic Medicine and Reconstructive Surgery ("FPMRS"). *Id.* Doctors like Dr. Jeppson "are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015).

A product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." Restatement (Third) of Torts: Product Liability § 2, cmt. j; *see also* Restatement (Second) of the Law of Torts § 388(b) & 402A, cmt. j. The test is an objective one that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (noting that manufacturers had a duty to warn only of dangers "not well known to the medical community"). In fact, the FDA device regulations say that information may be omitted

from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. § 801.10(c).

Thus, Dr. Jeppson need not have prior experience drafting IFUs or dealing with FDA labeling requirements. The relevant inquiry is what risks were commonly known to urogynecologists performing surgeries with these devices. On this point, Dr. Jeppson is imminently qualified to offer testimony.

Furthermore, Dr. Jeppson is qualified to offer his opinions as to whether certain risk factors—which Plaintiffs allege exist and should have been included in the IFUs—exist based upon his clinical experience and review of the medical literature. A physician with Dr. Jeppson's experience is allowed to rely upon his clinical experience and examine the literature to offer opinions as to the safety, effectiveness, and risk factors of the relevant products. *See, e.g.*, *Tyree*, 54 F. Supp. 3d at 585 (permitting board-certified urologist to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures" and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); 2015 WL 2087048, at *24 (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit"); *Bellew v. Ethicon*, No. 2:13-CV-22473, 2014 WL 1268596, at *19 (S.D.W. Va. Nov. 20, 2014) (rejecting the argument that Dr. Robboy's safety and efficacy opinions were improperly anecdotal and finding they reliably founded upon his clinical experience and review of scientific literature). This Court has allowed physicians to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *See, e.g., In re: Ethicon*

Inc., MDL No. 2327, 2016 WL 4547053, at *3 (S.D.W. Va. Aug. 31, 2016) (allowing Dr. Grier to provide the same type of IFU and warnings opinions that Dr. Jeppson offers here).

In short, Dr. Jeppson is qualified to testify as to the risks associated with the products at issue, whether certain risks existed or were well-known to surgeons, and whether those risks appeared on the relevant IFUs. Plaintiffs' motion should be denied.

B. Dr. Jeppson need not know the full regulatory history of each product to provide his opinions here.

Plaintiffs argue that because Dr. Jeppson could not recite the full regulatory history of the TVT product line from memory at his deposition, then he should be precluded from opinion about the safety and efficacy of such devices in his experience. Doc. 8325 at 8-9. This argument is fodder for cross examination and not for exclusion of Dr. Jeppson's opinions here. *See, e.g.*, *Trevino v. Boston Sci. Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *13 (S.D.W. Va. May 19, 2016) (finding Dr. Shull qualified to offer opinions as to the completeness and accuracy of the warnings, despite unfamiliarity with the regulatory history or FDA procedures).

Plaintiffs' reliance on *Sanchez* is misplaced. *See Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014). In *Sanchez*, a pharmaceutical consultant, Peggy Pence, Ph.D., sought to offer an opinion that Boston Scientific Corporation's ("BSC") product labeling practices fell below the standard of care. *Id.* at *35. The problem there was that Dr. Pence used "FDA regulations to craft criteria for the information that should be included in medical device labeling." *Id.* But like this case, the requirements of the FDA were not at issue there. *Id.* Thus, the Court concluded:

> The jury might think that the FDA regulations *govern* warning requirements in California, whereas Dr. Pence is actually using the FDA regulations as a *model* for the contents of labeling materials. Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations.

Id. (emphasis in original). Because "the only basis for Dr. Pence's opinions on the adequacy of BSC's product labeling [was] violation of the FDCA and FDA regulations," which was not probative to the claims at issue, the Court excluded such testimony. *Id.* at 36.

Dissimilarly, Dr. Jeppson here offers testimony as to what risk factors existed, were known to pelvic surgeons, and were included or excluded from the product warnings. This testimony is not based upon the regulatory history, and it is not based upon FDA requirements or compliance therewith. This testimony goes to the heart of the inquiry on Plaintiffs' failure to warn claim. As explained above, Dr. Jeppson is perfectly qualified to offer this kind of opinion testimony.

Conclusion

Defendants respectfully request that this Court strike and/or deny as moot the Wave 10 Plaintiffs' *Daubert* motion as to Dr. Jeppson. Further, Defendants ask that the Court deny the motion on the merits.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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